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| 10/554,166 | 10/21/2005 | Ronan F. Power | 180-050 | 6592 |
| 1009 7590 04/03/2009 KING & SCHICKLI, PLLC 247 NORTH BROADWAY LEXINGTON, KY 40507 | | | | |
| EXAMINER BADR, HAMID R | | | | |
| ART UNIT 1794 | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/554,166

Applicant(s)

POWER, RONAN F.

Examiner

HAMID R. BADR

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,12-19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,12-19 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S506)
Paper No(s)/Mail Date 12/30/2008.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' amendment filed on 01/21/2009 is acknowledged.

Claims 1-3, 5-10, 12-19 and 21 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 14-19 and 21 are indefinite for "a suitable feed grade carrier". It is unclear what is meant by "suitable" or what type of carriers are considered suitable.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-10, 12-19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Labeille et al. (US 2002/0037342; hereinafter R1).

3. R1 discloses a multi-enzyme product containing glucoamylase, proteolytic and xylanase activities. The product is prepared through the solid state fermentation of wheat bran using *Aspergillus niger* strain. The product is useful as animal feed.

(Abstract).

4. R1 discloses that wheat bran is used as the starting material which is moistened and heat treated to pasteurize it [0025, 0027].

5. R1 teaches adjusting the pH of the substrate to improve the efficiency of the pasteurization process and the initiation of the desired fermentation [0028].

6. R1 discloses that the fermentor should be aerated in order to supply the oxygen necessary for fermentation and to avoid the excessive accumulation of carbon dioxide produced by fermentation [0035]. Given that the fungus utilizes the carbon source for metabolism, a substantial quantity of dry matter is lost in the form of carbon dioxide. As a result the nitrogen content of the substrate will increase due to the loss of dry matter. The quality and digestibility of the protein source will improve due to the action of the proteolytic enzyme. Therefore, the decrease in dry matter and fat content and the increase in nitrogen content with an improved nutritional quality are all inherent in the fermentation process.

7. R1 discloses that the product of the fermentation process is a solid product [0037]. Given that the substrate and the fungus interact to produce a solid product, the solid state fermentation concept applies.

8. R1 discloses that a possible use of the product is the production of wheat-based feed for monogastric animals such as poultry and pigs.[0038]

9. R1 teaches of freezing or drying the product for storage [0039]
10. R1 teaches that at the end of the fermentation process, the enzymes produced during the course of fermentation can be solublized in aqueous medium and separated by filtration [0082]. Given that the produced enzymes can be separated from the fermented substrate, it is clear that it can be frozen or dried for future use.
11. R1 discloses that an increase is observed in the soluble nitrogen content of the fermented bran due to the proteolytic activity. [0143] The results indicate that the fermented brans are capable of hydrolyzing wheat flour with the same efficacy as a standard preparation [0144]. Therefore, it is clear that a composition containing a protease can be added to animal feed to increase the digestibility of proteins in the feed.
12. R1 discloses that the incorporation of fermented bran into poultry feed made it possible significantly to reduce the feed conversion ratio [0159]. This means that the animal gains weight while consuming a lower quantity of feed.
13. R1 discloses that the use of the fermented bran nevertheless has the advantage of being less expensive than the use of the commercial enzymatic product [0159].

Response to Arguments

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

1. Applicants argue that Claims 14-19 and 21 are definite and that the term "suitable feed grade carrier" as used in the context of a disclosure relating to animal

feed is known in the art. Applicants further have attached a publication of American Feed Control Officials (1999) giving the definition of "carriers".

a. The meaning of the words "carrier" or "carriers" is known. It is also clear that the carrier should be feed grade. However, the indefiniteness rejection has been raised on the suitability of the carrier. The suitability of the carrier is neither clarified by the claims nor by the specification. These claims remain indefinite for that matter.

2. Applicants argue that Labeille (R1) neither teaches nor provides an articulated reason for the skilled artisan to consider the subject matter of the present independent claims as amended.

a. The data presented by R1 for the range of decrease in dry matter clearly overlaps the presently claimed range of 7-12%. (see R1 Table 6). The claimed ranges for protein and fat content of the fermented product will be inherent regarding the fermentation duration range of 0-66 hours as disclosed by Labeille.

3. Applicants argue that Labeille (R1) focuses on the enzyme content of the product.

a. Labeille discloses a process for solid state fermentation of fibrous materials using filamentous fungi in which multiple enzymes including the presently claimed protease are produced. Enzymes are the focus of certain embodiments of the invention, however, Labeille clearly demonstrates the use of the fermented material as animal feed emphasizing the improved nutritional quality of the product with specific reference to

reduction in the feed conversion ratio resulting in the weight gain by the animal.

Therefore, Labeille discloses all aspects of the presently claimed invention.

4. Applicants argue that Labeille is silent on any alterations in protein or fat content of the substrates and that for at least this reason, it cannot be said that Labeille anticipates the present independent claims as amended.

a. Applicants' attention is drawn to the biochemistry of the solid state fermentation involving filamentous fungi. Usually in such fermentations the carbon to nitrogen ratio is greater than 1. The reason is of-course the higher requirement for carbon source. In the aerobic fungal fermentation of cellulosic (fibrous) substrates, plenty of carbon dioxide is evolved due to the metabolism of carbohydrates. This will cause a pronounced decrease in the dry matter of the materials being fermented. Lipid materials will also be metabolized and a decrease in lipid materials will also be inherent in the fungal fermentations. The extent of fat metabolism and the subsequent decrease in lipid concentration will depend on the raw starting materials. However, while nitrogenous materials contained in the substrate being fermented, are metabolized, they are mostly utilized by the fungus for synthesis of new cellular materials, enzymes and compounds requiring nitrogen in their structures. It is clear that decrease in dry matter involving carbon sources (carbohydrates and fats) will inherently increase the protein content based on the dry matter. Therefore, while Labeille is not expressly mentioning protein and fat content the nature of the process as disclosed by Labeille will necessitate the inherent biochemical changes in carbohydrates, fats and proteins as presently claimed.

5. Applicants argue that given the enzyme focus of the Labeille disclosure, the skilled artisan is provided no articulated reason to consider the particular alterations in protein, fat and dry matter to improve nutritional properties of the by product or residue as expressly claimed herein.

a. In a specific embodiment, Labeille discloses the improved nutritional quality of the fermented cellulosic substrate and concludes that the supplemented feed shows a decrease in the feed conversion ratio. In other words, more weight is gained by the animal upon consuming less feed.

On the other hand since the fungal fermentations will cause the fibrous agricultural by-products to increase in protein, it is clear that the improved nutritional quality will be an inherent property of such fermented products.

6. Applicants argue that Labeille teaches away from the present invention because Labeille discloses a decrease of dry matter of 23% which is outside the scope of the present claims.

a. The range of decrease in dry matter as disclosed by Labeille is discussed above under 2a. Additionally, paragraph 140 refers to a loss in dry matter after 60 hours of culture, however, this is just one specific example of Labeille for one specific culture time. A fair reading of the reference as a whole discloses that culturing can occur for a period of 1-3 days and that from 24-37 hours, for instance, as disclosed by Table 6, it is clear that the amount of decrease in dry matter does fall within the amount claimed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:30 to 4:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794